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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10443 and CMS-10149]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: New collection. Title of Information Collection: Transcatheter Valve Therapy Registry and KCCQ-10. Use: The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, "Transcatheter Aortic Valve Replacement (TAVR)". The TAVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all cause mortality and

quality of life. CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis.

The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ-10) to assess health status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0-100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ-10 is in accordance with Section 1142 of the Social Security Act (the Act) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine

if the TAVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, The TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. Form Number: CMS-10443 (OCN: 0938-New); Frequency: Annual; Affected Public: Individuals, Households and Private Sector; Number of Respondents: 12,000; Total Annual Responses: 24,000; Total Annual Hours: 7,000. (For policy questions regarding this collection contact JoAnna Baldwin at 410-786-7205. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Health Insurance Reform: Electronic Security Standards; Use: This information collection corresponds to existing regulations establishing standards for the security of electronic protected health information to be implemented by health plans, health care clearinghouses and certain health care providers, as required under title II, subtitle F, sections 261 through 264 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191. The use of the security standards improves Federal health programs, private health programs, and the effectiveness and efficiency of the health care industry in general by establishing a level of protection for certain electronic health information. This information collection request does not propose any changes to this information collection related to future modifications of the underlying HIPAA security

standards. Form Number: CMS-10149 (OCN: 0938-0949); Frequency: Occasionally; Affected Public: Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; Number of Respondents: 135,560; Total Annual Responses: 285,560; Total Annual Hours: 536,743. (For policy questions regarding this collection contact William Parham at 410-786-4669. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by **IOFR—insert date 60 days after date of publication in the Federal Register**:

1. Electronically. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: CMS-R-284 (OCN 0938-0345)

Room C4-26-05

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